

# 12 PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

|  |  |
|--|--|
| Date of mailing (day/month/year)<br>15 May 2000 (15.05.00)           |  |
| International application No.<br>PCT/US99/11497                      | Applicant's or agent's file reference<br>PF-0525 PCT     |
| International filing date (day/month/year)<br>25 May 1999 (25.05.99) | Priority date (day/month/year)<br>28 May 1998 (28.05.98) |
| Applicant<br>LAL, Preeti et al                                       |  |

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:  
16 December 1999 (16.12.99)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was  
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

|  |  |
|--|--|
| <p>The International Bureau of WIPO<br/>34, chemin des Colombettes<br/>1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p> | <p>Authorized officer<br/>R. Forax</p> <p>Telephone No.: (41-22) 338.83.38</p> |
|--|--|

# PATENT COOPERATION TREATY

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| International filing date (day/month/year)<br>25 May 1999 (25.05.99) | Priority date (day/month/year)<br>28 May 1998 (28.05.98) |
| Applicant<br>LAL, Preeti et al                                       |  |

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made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

R. Forax

Telephone No.: (41-22) 338.83.38

# PATENT COOPERATION TREATY

## PCT

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

|   |   |  |   |
|---|---|--|---|
| Applicant's or agent's file reference<br><b>PF-0525 PCT</b> | <b>FOR FURTHER ACTION</b>                                       |  | see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below. |
| International application No.<br><b>PCT/US 99/ 11497</b>    | International filing date (day/month/year)<br><b>25/05/1999</b> | (Earliest) Priority Date (day/month/year)<br><b>28/05/1998</b> |   |
| Applicant<br><br><b>INCYTE PHARMACEUTICALS, INC. et al.</b> |   |  |   |

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 7 sheets.  
☐ It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).
- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :
- ☒ contained in the international application in written form.
- ☒ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☒ **Unity of invention is lacking** (see Box II).

**4. With regard to the title,**

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established by this Authority to read as follows:

**5. With regard to the abstract,**

- ☒ the text is approved as submitted by the applicant.
- ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

**6. The figure of the drawings to be published with the abstract is Figure No.**

- ☐ as suggested by the applicant.
- ☐ because the applicant failed to suggest a figure.
- ☐ because this figure better characterizes the invention.

☐ None of the figures.

# INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 11497

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:

See FURTHER INFORMATION sheet PCT/ISA/210

2. ☒ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

See FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See additional sheet.

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Claims 1-16, 19 (all partially)

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

**FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210**

Continuation of Box I.2

Claims Nos.: 17, 18, 20

Claims 17, 18, 20 have not been searched due to insufficient disclosure of the claimed compounds.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

## FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

## 1. Claims: 1-16, 19 (all partially)

A substantially purified polypeptide comprising amino acid sequence SEQ ID NO. 1 and fragments thereof, a variant having at least 90% identity; an isolated and purified polynucleotide encoding said polypeptide; a variant of said polynucleotide having at least 90% identity; a polynucleotide which hybridizes under stringent conditions to said polynucleotide; a polynucleotide having a sequence which is complementary to said polynucleotide; a method for detecting a polynucleotide encoding said polypeptide; said method wherein the polynucleotide is amplified by applying PCR; an isolated and purified polynucleotide comprising polynucleotide sequence SEQ ID NO. 10 and fragments thereof, or a variant having at least 90% identity; a polynucleotide having a sequence which is complementary to said polynucleotide; an expression vector comprising at least a fragment of said polynucleotide; a host cell comprising said expression vector; a method for producing a polypeptide comprising amino acid sequence SEQ ID NO. 1; a pharmaceutical composition comprising said polypeptide in conjunction with a suitable pharmaceutical carrier; an antibody which specifically binds to said polypeptide.

## 2. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 2 and 11.

## 3. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 3 and 12.

## 4. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 4 and 13.

## 5. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 5 and 14.

## 6. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 6 and 15.

## 7. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 7 and 16.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

8. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 8 and 17.

9. Claims: 1-16, 19 (all partially)

Same as subject 1 but limited to SEQ ID NOS. 9 and 18.

# INTERNATIONAL SEARCH REPORT

International Application No

T/US 99/11497

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/12 C07K14/47 A61K38/17 G01N33/68 C12Q1/68  
C07K16/18

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C07K C12N A61K G01N C12Q

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages  | Relevant to claim No. |
|------------|---|-----------------------|
| X          | WO 98 20023 A (INST MEDICAL W & E HALL<br>;VINEY ELIZABETH M (AU); STARR ROBYN<br>(AU);) 14 May 1998 (1998-05-14)<br>see SEQ ID NO: 24-27 (pp. 142-147)<br>see the claims<br>abstract; examples 5-8,11,18-24,28; table<br>7.1<br>page 4 -page 5<br>page 17 -page 18<br>page 33<br>---<br>-/-- | 1-16,19               |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

- \*A\* document defining the general state of the art which is not considered to be of particular relevance
- \*E\* earlier document but published on or after the international filing date
- \*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- \*O\* document referring to an oral disclosure, use, exhibition or other means
- \*P\* document published prior to the international filing date but later than the priority date claimed

- \*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- \*Z\* document member of the same patent family

Date of the actual completion of the international search

21 September 1999

Date of mailing of the international search report

1 3. 01. 00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Oderwald, H



## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/11497

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category ° | Citation of document, with indication, where appropriate, of the relevant passages   | Relevant to claim No. |
|------------|--|-----------------------|
| X          | DATABASE EMBEST16 [Online]<br>EMBL, Heidelberg, Germany<br>AC: AA401503, ID: HS1200297,<br>29 April 1997 (1997-04-29)<br>HILLIER L ET AL.: "Homo sapiens cDNA clone<br>742641"<br>XP002115960<br>abstract<br>---   | 3-13                  |
| X          | WO 92 19734 A (INDIANA UNIVERSITY<br>FOUNDATION ;UNIV YALE (US))<br>12 November 1992 (1992-11-12)<br>see SEQ ID NO: 33 and 34 (pp.145-151)<br>abstract; claims<br>1,21,31,33,63-65,75,84,95,99,103,111,119;<br>figure 24<br>page 17 -page 19<br>---  | 3-14,16               |
| A          | D J HILTON ET AL: "Twenty proteins<br>containing a C-terminal SOCS box form five<br>structural classes"<br>PROCEEDINGS OF THE NATIONAL ACADEMY OF<br>SCIENCES OF USA,<br>vol. 95, 1 January 1998 (1998-01-01),<br>pages 114-119, XP002085497<br>ISSN: 0027-8424<br>cited in the application<br>the whole document<br>----- |                       |

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/11497

| Patent document<br>cited in search report | Publication<br>date | Patent family<br>member(s) | Publication<br>date |
|---|---------------------|----------------------------|---------------------|
| WO 9820023 A                              | 14-05-1998          | AU 4694397 A               | 29-05-1998          |
|   |                     | EP 0948522 A               | 13-10-1999          |
|   |                     | GB 2331753 A               | 02-06-1999          |
|   |                     | NO 992116 A                | 29-06-1999          |
| WO 9219734 A                              | 12-11-1992          | AU 675203 B                | 30-01-1997          |
|   |                     | AU 1919792 A               | 21-12-1992          |
|   |                     | CA 2102208 A               | 12-11-1992          |
|   |                     | EP 0576623 A               | 05-01-1994          |
|   |                     | EP 0933082 A               | 04-08-1999          |
|   |                     | EP 0930365 A               | 21-07-1999          |
|   |                     | EP 0930366 A               | 21-07-1999          |
|   |                     | JP 7503123 T               | 06-04-1995          |
|   |                     | US 5648464 A               | 15-07-1997          |
|   |                     | US 5849869 A               | 15-12-1998          |
|   |                     | US 5856441 A               | 05-01-1999          |
|   |                     | US 5789195 A               | 04-08-1998          |

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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|  |  |   |
|--|--|---|
| Applicant's or agent's file reference<br>PF-0525PCT  | FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |   |
| International application No.<br>PCT/US99/11497  | International filing date (day/month/year)<br>25 MAY 1999  | Priority date (day/month/year)<br>28 MAY 1998 |
| International Patent Classification (IPC) or national classification and IPC<br>IPC(7): C07K 2/00 and US Cl.: 536/23.1; 435/6, 520.1 |  |   |
| Applicant<br>INCYTE PHARMACEUTICAL   |  |   |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets.
- ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of report with regard to novelty, inventive step or industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

|  |   |
|--|---|
| Date of submission of the demand<br>16 DECEMBER 1999   | Date of completion of this report<br>09 APRIL 2001          |
| Name and mailing address of the IPEA/US<br>Commissioner of Patents and Trademarks<br>Box PCT<br>Washington, D.C. 20231 | Authorized officer<br><i>Hope Robinson</i><br>HOPE ROBINSON |
| Facsimile No. (703) 305-3230   | Telephone No. (703) 308-0196                                |

Form PCT/IPEA/409 (cover sheet) (July 1998)\*

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/11497

## I. Basis of the report

1. With regard to the elements of the international application:\*

☒ the international application as originally filed

☒ the description:

pages 1-67, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of

☒ the claims:

pages 68-69, as originally filed

pages NONE, as amended (together with any statement) under Article 19

pages NONE, filed with the demand

pages NONE, filed with the letter of

☒ the drawings:

pages NONE, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of

☒ the sequence listing part of the description:

pages 1-19, as originally filed

pages NONE, filed with the demand

pages NONE, filed with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.  
These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☒ contained in the international application in printed form.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☒ The amendments have resulted in the cancellation of:

☒ the description, pages NONE

☒ the claims, Nos. NONE

☒ the drawings, sheets/fig. NONE

5. ☐ This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\*Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/US99/11497

## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been and will not be examined in respect of:

☐ the entire international application.

☒ claims Nos. 17, 18 and 20

because:

☐ the said international application, or the said claim Nos. \_ relate to the following subject matter which does not require international preliminary examination (*specify*).

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_ are so unclear that no meaningful opinion could be formed (*specify*).

☐ the claims, or said claims Nos. \_ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 17, 18 and 20.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/US99/11497

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. statement

Novelty (N)

Claims NONE

YES

Claims 1-16, 19

NO

Inventive Step (IS)

Claims NONE

YES

Claims 1-16, 19

NO

Industrial Applicability (IA)

Claims 1-16, 19

YES

Claims NONE

NO

### 2. citations and explanations (Rule 70.7)

Claims 1-16 and 19 lack novelty under PCT Article 33(2) as being anticipated by Viney et al. (WO 98/20023).

Viney discloses molecules that modulate signal transduction and in particular disclose SEQ ID NO: 24-27 that match at least 90% identity with nucleic acid and amino acid sequences disclosed in the instant application for use as therapeutics and diagnostics (see abstract and pages 142-147). In addition, Viney teaches hybridization under stringent conditions, a protein comprising a SOCS box in its C-terminal region, a method of use for modulating cytokines signal transduction (see claims, abstract and examples 5-8, 11, 16-24 and 25-29, pages 4-6, 17-19 and 33).

Claims 3-14 and 16 lack an inventive step under PCT Article 33(3) as being obvious over INDIANA UNIVERSITY FOUNDATION (WO 92/19734). The reference teaches a nucleic acid and amino acid sequence (SEQ ID NO: 33 and 34) which have a 90% identity to the sequences disclosed in the instant application (see pages 145-51). In addition, the reference teaches fragments, vectors, a recombinant host cell, a method of producing the protein and an antibody (see claims 1, 21, 31, 33, 63-65, 75, 81, 82, 84, 95, 99, 103, 111, 112-115 and 115, Figure 24 and pages 17-19).

NEW CITATIONS

NONE